#16
B. Webb
1/6/04

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:	
Michael Norman COLLINS	:	
Serial No. 09/989,393	:	Art Unit: 3761
Filed: November 21, 2001	:	Examiner: Mendoza, Michael G.
For: LARYNGEAL MASK ASSEMBLIES	:	Atty Docket: 0100/0139

DECLARATION

I, MICHAEL NORMAN COLLINS, a British citizen of Hollydene, Canterbury Road, Lyminge, Folkestone, Kent CT18 8HD, England do hereby solemnly and sincerely declare as follows:

1. I joined Portex Limited in May 1973 and worked there until March 2003. In my last position at Portex Limited I was Principal Engineer. I am now retired.

2. Portex Limited is a wholly owned subsidiary of Smiths Group plc of 765 Finchley Road, London NW11 8DS, England.

3. One of my responsibilities at Portex was to develop a laryngeal mask. A laryngeal mask is used to ventilate a patient during anaesthesia. The laryngeal mask was first invented by Archibald Brain around 1982. Portex has long experience in the

manufacture of patient ventilation products but has not previously sold a laryngeal mask.

4. When I started work on designing a laryngeal mask around May 1999, the only laryngeal mask being sold worldwide was made by Archibald Brain's company "The Laryngeal Mask Company."

5. The laryngeal mask sold by Brain's company comprised a tubular shaft, a separate, shoe-like mount attached to the patient end of the shaft and an inflatable, annular cuff secured to the mount. A small-bore inflation tube opened into the cuff to enable it to be inflated and deflated. The product was essentially as described in US4509514, which is now produced and shown to me marked "MNC1".

6. The first product sold by Brain's company was made of rubber (the LMA-Classic) and was intended to be reusable although more recently it has introduced a single-use, plastics product (the LMA-Unique). These existing laryngeal masks were relatively expensive, the cost of the reusable mask being about £80 (about US$120) and the cost of the single-use mask being about £20 (about US$30).

7. US5241956, which is now produced and shown to me marked "MNC2", describes another, more complex laryngeal mask having additional features but this also has its cuff secured to a mount that is formed separately of the shaft.

8. The high cost of the laryngeal masks compared with alternative ventilation products meant they were only used in relatively limited numbers for specialised procedures.

9. In designing the Portex laryngeal mask our aim was to produce a single-use product that would perform well and could be sold at a lower cost.

10. My colleagues and I considered many different forms of construction as can be seen by the various specifications and abstracts of patent applications we filed between 1995 and 2000, as illustrated by the bundle which is now produced and shown to me marked "MNC3".

11. I believed, however, that the best form of construction would be if we could make the shaft and mount together by moulding as a single piece. It was by no means obvious that such a construction was possible in commercial production for the following combination of factors:

a) First, the mask is a relatively large product for injection moulding;

b) Second, the wall thickness of a single piece mask would need to vary considerably in different locations and around a curved section;

c) Third, it is difficult to mould accurately from the soft grade of plastics materials required in a laryngeal mask;

d) Fourth, the need to mould from soft grade plastics could be perceived as making it difficult to achieve the optical clarity desirable in a laryngeal mask, although we have found that the necessary clarity can be achieved; and

e) Fifth, the complex shape of the mould tool needed to make a laryngeal mask in one piece and possible problems in removing the moulded product from the tool might be seen as too difficult to achieve, especially where it is important to produce a very smooth surface finish.

12. Despite my misgivings I was pleased that we were able to produce a high quality product by injection moulding the shaft and mount as a single piece. It is my belief that we extended the technology beyond what was the current state of the art.

13. We found that this gives us many advantages. As intended, it means that we avoid the need to assemble the mount onto the shaft. This avoids an assembly step, thereby reducing manufacturing costs, and also avoids the need to test the joint between the shaft and the mount and completely avoids any risk of separation between the two components.

14. A further, unexpected advantage is that it enables us to control the flexibility of the mask much more precisely along the entire length of the mask. The joint between the mount and shaft of a conventional laryngeal mask makes the region of the joint thicker and stiffer, thereby leading to an abrupt transition in flexibility on either side of the joint. This is completely avoided in the Portex laryngeal mask as can be seen in the sample of the mask which is now produced and shown to me marked "MNC4". By selecting the ideal flexibility at all points along the length of the mask we ensure that

the mask conforms to the patient's anatomy in the best manner and that the mask can be inserted in a reliable manner.

15. By avoiding the need for any joint between the shaft and mount, the outside of the Portex tube can be completely smooth in the pharyngeal region, thereby reducing the risk of trauma to the patient.

16. Moreover, there is an additional advantage in that it greatly facilitates assembly of the small-bore inflation line because the groove in which this is fitted can be moulded along the length of the product, avoiding any need to align grooves in separate components and avoiding any step transition. The ends of the groove terminate in a shape that is moulded and consistent, a factor that has contributed to the reliability of the product.

17. The Brain mask available at the time I made this invention had an inflation line extending loosely from the cuff. This was perceived as being a disadvantage because of the risk the inflation line could become tangled in the mouth, such as with the teeth. Because our form of construction enabled us easily to attach the inflation line to the main shaft it gave our laryngeal mask an appreciable advantage over the Brain product.

18. Portex started selling its laryngeal mask under the Soft Seal name in Australia in May 2002 and started selling it into the USA in January 2003. The product is substantially

as described in my pending US patent application SN 09/989,393. The product has been well received. As evidence of this there is now produced and shown to me marked "MNC5" an article in the eminent US journal "Anesthesiology", which is one of the most important journals in this field. This describes a comparative study between the Portex disposable "Soft Seal" laryngeal mask and the reusable LMA-Classic mask made by The Laryngeal Mask Company. The article states in conclusion that the Portex product "is an acceptable alternative to the reusable LMA-Classic, resulting in a good laryngeal seal and offering similar clinical performance. Cuff pressures increase substantially when the LMA-Classic is used but not when using the Soft-Seal LM. There was less trauma to patients using the Soft Seal LM, as assessed by the incidence of sore throat in the early postoperative period."

19. Although the Portex Soft Seal laryngeal mask has only recently been introduced, I have been told that sales are increasing well and that the future prospects for the product are excellent.

20. In summary, I believe that, at the time my patent application was filed, it was far from obvious that a laryngeal mask could be made commercially by moulding the mount and shaft together. Furthermore, the invention has produced real, practical advantages and commercial success, which would not have been immediately apparent at the time the patent application was filed.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true;

and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 3.12.03

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Exhibit MNC1

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Exhibit MNC2

Michael Norman Collins

Date: 5.12-03

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Exhibit MNC3

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Exhibit MNC4

Michael Norman Collins

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Exhibit MNC5

Michael Norman Collins

Date: 5.12.03

LIPPINCOTT WILLIAMS & WILKINS
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Comparison of the LMA-Classic™ *with the New Disposable Soft Seal Laryngeal Mask in Spontaneously Breathing Adult Patients*

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Background: **The laryngeal mask airway *LMA-Classic*™ has been used widely in clinical practice. A new disposable supraglottic airway device, the Soft Seal LM, has been introduced recently. In a randomized study, the authors compared the *LMA-Classic*™ and the disposable Soft Seal LM in terms of their clinical performance, cuff pressures during nitrous oxide anesthesia, position of the laryngeal mask *in situ* by fiberoptic evaluation, and morbidity in a wide range of routine general surgery procedures.**

Methods: **A total of 200 adult patients were randomly assigned to a size 4 laryngeal mask in two equal-sized groups for airway management during surgery: (1) *LMA-Classic*™ (Intavent Orthofix Ltd., Maidenhead, Berkshire, United Kingdom); or (2) Soft Seal LM (Portex Ltd., Hythe, Kent, United Kingdom). Anesthesia was administered with fentanyl, propofol, nitrous oxide, oxygen, and sevoflurane. The variables studied were ease of insertion, fiberoptic view, time *in situ*, incidence of blood on the laryngeal mask at the time of removal, and the incidence of postoperative sore throat at 2 and 24 h. The laryngeal mask cuff pressures were measured continuously. Intracuff pressure limitation was not attempted.**

Results: **The *LMA-Classic*™ and the Soft Seal LM showed similar clinical performances, as shown by their insertion time (successful insertion at first attempt was achieved within 20 s in 97% with *LMA-Classic*™ *vs.* 95% with Soft Seal LM), fiberoptic evaluation of the anatomic position of the laryngeal mask, and satisfactory anesthesia conditions. Laryngeal mask cuff pressures increased from 45 to 100.3 mmHg in the *LMA-Classic*™ and from 45 to 46.8 mmHg in the Soft Seal LM ($P < 0.001$). Macroscopic blood was seen on only four occasions in the *LMA-Classic*™ group. The incidence of sore throat was significantly increased at 2 h postoperatively when using the *LMA-Classic*™, although there was no difference at 24 h after surgery.**

Conclusions: **In spontaneously breathing adult patients requiring a size 4 laryngeal mask airway, the new disposable Soft Seal LM device is an acceptable alternative to the reusable *LMA-Classic*™, resulting in a good laryngeal seal and offering similar clinical performance. Cuff pressures increase substantially when the *LMA-Classic*™ is used but not when using the Soft Seal LM. There was less trauma to patients using the Soft Seal LM, as assessed by the incidence of sore throat in the early postoperative period.**

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THE reusable laryngeal mask airway (*LMA-Classic™*, Intavent Orthofix Ltd., Maidenhead, Berkshire, United Kingdom) has been available since 1988, and it is now widely used for airway management during elective general anesthesia not requiring tracheal intubation. A single-use laryngeal mask airway (*LMA-Unique™*, Intavent Orthofix Ltd.) has been available since 1997, and it has been found to be similar in performance to the reusable laryngeal mask.[1-4] There is growing concern regarding the ability to clean reusable laryngeal masks effectively and consequently their safety.[5-10]

A new single-use disposable supraglottic airway device, the Soft Seal LM (Portex Ltd., Hythe Kent, United Kingdom), has been introduced recently (fig. 1). It is fabricated from latex-free medical-grade plasticized polyvinyl chloride (PVC). To our knowledge, no studies have been published so far assessing this device. The characteristics of the two laryngeal masks are presented in table 1.

The primary aim of this study was to evaluate the clinical acceptability of the new device, the Soft Seal LM, as an alternative to the *LMA-Classic™*. We compared the masks in terms of ease of insertion, cuff pressure changes, position *in situ* by fiberoptic evaluation, and morbidity.

Materials and Methods

After institutional review board approval (Catharina Hospital Eindhoven) and informed patient consent, we prospectively studied 200 unselected, consecutive, supine anesthetized patients who were scheduled to undergo elective surgery with the use of a laryngeal mask. Patients aged 18-80 yr were included in the study. Patients were excluded if they had an American Society of Anesthesiologists physical status class of III to V; required surgery in a nonsupine position or had to undergo oral or nasal surgery; had a preoperative sore throat; had a known or predicted difficult airway, chronic obstructive pulmonary disease, or respiratory tract pathology; or were considered unsuitable for surgery with the use of a laryngeal mask.

Patients were allocated randomly, using computer-generated tables of random numbers, to a size 4 laryngeal mask and received either the silicone rubber reusable *LMA-Classic™* or the disposable Portex Soft Seal LM. All laryngeal masks were inserted for a wide range of routine general surgery, orthopedic, urologic, gynecologic, and plastic surgery. Patients were unaware of the airway

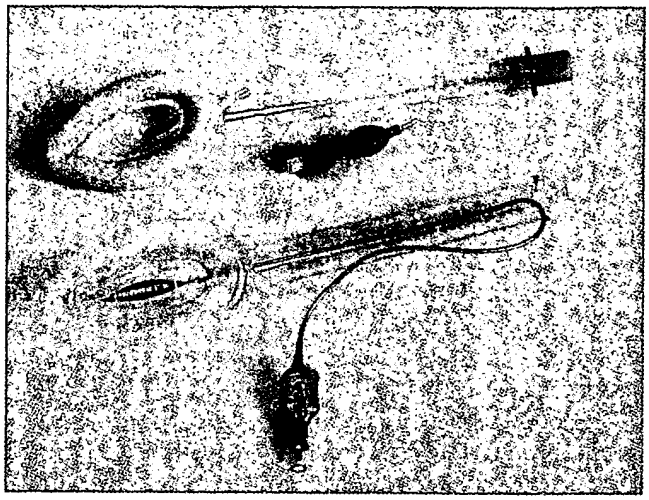

Fig. 1. The reusable *LMA-Classic*™ and the disposable Soft Seal LM. Note the same dimensions of the cuff, whereas the diameter of the tube and the depth of the bowl are larger in the disposable laryngeal mask. The inflation line is integrated in the disposable version while separate in the *LMA-Classic*™. Two laryngeal bars are present in the *LMA-Classic*™ but absent in the disposable Soft Seal LM. Note the size of the product and maximum cuff inflation volume (< 35 ml) printed on the pilot balloon of the Soft Seal LM.

device used. The *LMA-Classic*™ masks used were normal clinical-use products in our hospital. The Soft Seal LMs were all new, as they were used only once. At our institution, the *LMA-Classic*™ is the standard supraglottic airway device. All laryngeal masks in both groups were inserted by the same anaesthesiologist (A. V. Z.; personal experience: more than 2,500 *LMA-Classic*™ masks and 80 Soft Seal LMs inserted before the study).

Routine preinsertion tests of the cuff for leaks, as recommended by the manufacturers, were done immediately before use. The tip of the laryngeal mask as well as the posterior aspect of the mask was coated with a water-soluble lubricant with 2% lidocaine (Instillagel; Farco-Pharma, Cologne, Germany), which is the normal practice in our institution. The cuff was inflated before insertion with ambient room air at 10 mmHg (15 cm H_2O) above atmospheric pressure, which is the standard practice in our institution and advocated by many authors.[3,11–18]

No premedication was used, and all patients were preoxygenated for 3 min before intravenous induction. Intravenous induction of general anesthesia consisted of 1 μg/kg fentanyl and 3 mg/kg propofol. The lungs were ventilated manually with sevoflurane (end-tidal 2%–3%) added to a mixture of 66% N_2O in oxygen administered *via* a facemask without the use of an oral airway. The laryngeal mask was inserted 1 min after completion of induction and after loss of lash reflex and the relaxation of the jaw.[19] An insertion attempt was defined as placement of the laryngeal mask in the mouth and withdrawal of the device from the mouth. Successful placement of an effective airway and adequate ventilation was confirmed by the presence of resistance to further downward movement, observing chest wall movement with manual ventilation, listening to the escape of gas from the mouth, detection of a square wave trace capnograph during manually assisted ventilation, and observation of movement of the reservoir bag on spontaneous ventilation. The ease of insertion of the laryngeal mask was

Table 1. Characteristics of Reusable *LMA-Classic*™ and Disposable Soft Seal LM, Size 4

	Reusable *LMA-Classic*™	Disposable Soft Seal LM
Material	Silicone rubber	Medical grade PVC
	Silicone rubber cuff	Soft Seal PVC cuff
	Translucent–opaque tube	Translucent tube
	Two pieces	Smooth one-piece device
	"Step" between tube and shoe	No "step" between tube and shoe
Inflation line	Separate–on cuff	Integrated with tube
	Can become tangled with other lines and teeth	Attached close to 15-mm connector
Marking	Black line	Blue line
Dimensions		
Cuff	90 × 55 mm	90 × 55 mm
Tube	11.0 mm ID	11.0 mm (internal)
	16.0 mm OD	17.6 mm (external)
Volume tube	20 ml	33.5 ml
Epiglottis bars	Two	None
Insertion of ETT (*in vitro*)	Up to 6.0 mm	Up to 7.0 mm
Use of flexible fiber-optic device through LM	Easy to use	Easy to use
Cost		
Device acquisition	140 €	10–12 €
Sterilization/cleaning	2.72 €	Not applicable
Removal of LM	Requires immersion in water to prevent encrustation of residues	Hospital clinical waste system
	Requires expensive time-consuming cleaning, washing, and sterilizing	

ETT = endotracheal tube; LM = laryngeal mask; PVC = polyvinyl chloride.

graded as (1) very easy insertion at the first attempt with no resistance; (2) easy insertion at the first attempt with little resistance; (3) some difficulties, but successful at the second attempt; or (4) not successful.

When the black line (*LMA-Classic™*) or blue line (Soft Seal LM) was centrally positioned, the laryngeal mask pilot balloon cuff pressure was adjusted to 45 mmHg (60 cm H_2O) as recommended,[20–24] using a hand-held pressure gauge to monitor the initial cuff pressure in cm H_2O (Endotest; Rüsch, Kernen, Germany) and a pressure transducer (AS/3; Datex-Ohmeda, Helsinki, Finland) to measure the cuff pressure continuously in mmHg. The laryngeal mask was securely fixed using tape with a bite block. Subsequently, the seal around the larynx by the laryngeal mask was checked for any air leak by ventilating the patient against an outlet valve pressure of 15 mmHg (20 cm H_2O).[25] For that reason, we closed the expiratory valve of the circle system at a fixed gas flow of 3 l/min and noted the airway pressure at which equilibrium was reached. Any air entering the stomach was noted when measuring oropharyngeal leak pressure by listening over the epigastrium with a stethoscope. When the laryngeal mask was considered to function adequately, allowing the patient to breathe spontaneously (sevoflurane–nitrous oxide–oxygen) with end-tidal carbon dioxide levels between 4.0 and 6.0, a fiberscope (StyletScope; Nihon Kohden, Tokyo, Japan) was inserted with its tip located at the inner aperture of the laryngeal mask. The position of the epiglottis was assessed using a standardized[25–26] four-point scale (1–4) as follows: grade 4, only vocal cords seen; grade 3, vocal cords and posterior epiglottis seen; grade 2, vocal cords and anterior epiglottis seen; grade 1, vocal cords not seen. Grade 3 and 4 positions were considered correct, whereas grades 1 and 2 were considered suboptimal positions.[25] All fiberoptic scoring was made within approximately 2 min of the laryngeal mask insertion. The presence of any aspirated or regurgitated material in the hypopharynx and the incidence of laryngeal spasm or other adverse events (coughing, retching, breath holding) were noted.

Anesthesia was maintained with a fresh gas flow of 3 l/min using 66% N_2O in oxygen and sevoflurane (end-tidal sevoflurane levels between 1.5% and 2%). Fentanyl, 0.05 mg, was added intravenously as required. When surgically indicated, but well after the insertion of the laryngeal mask airway and fiberoptic score, 0.5 mg/kg rocuronium was used as the neuromuscular blocking drug. Standard patient monitoring consisted of inspiratory and expiratory concentrations of nitrous oxide, oxygen, and sevoflurane; electrocardiogram; heart rate; capnography; noninvasive arterial blood pressure; peripheral oxygen saturation measured by pulse oximetry; respiratory rate; and tidal volume.

At the end of surgery, nitrous oxide and sevoflurane were discontinued to allow the patient to resume full recovery. When the protective reflexes had returned to normal, the laryngeal mask was removed synchronously with deflation of the cuff to 45 mmHg (60 cm H_2O) to avoid secretions entering the larynx or provoking laryngeal spasms.[21] On removal of the laryngeal mask, the presence or absence of blood was noted. Any blood on the mask or in the secretions on the mask was considered positive. Patients were requested to grade any sore throat at 2 and 24 h after surgery. Postoperative evaluations, including the evaluation of blood on the laryngeal mask, were performed by another anesthesiologist.

The following parameters of each patient were collected: sex, age, weight, height, type of surgery, time to insert the laryngeal mask, number of insertion attempts to achieve a satisfactory airway, and duration of laryngeal mask *in situ*. Laryngeal mask cuff pressures were monitored continuously, while intracuff pressure limitation was not practiced, with time 0 the moment the pilot cuff was inflated to a pressure of 45 mmHg until the moment nitrous oxide was switched off.

Statistical Analysis

We estimated the final cuff pressure difference between the *LMA-Classic™* and the Soft Seal LM to be 35% lower in the latter. Sample size calculation was performed using Sampsize version 2.0 (Sample Size tables for clinical studies; Blackwell Science Ltd., Oxford, United Kingdom). Ho: $\mu 1 = \mu 2$ (no difference between population means, two-sided hypothesis). The study had a power of 90% ($\beta = 10\%$; $\alpha = 0.05$), and the standardized difference was 0.35 (SD, 0.86). The estimated sample size was 88 patients per group. Two groups of 100 patients were chosen. Statistical analysis was performed using SPSS version 9.0 for Windows (SPSS Inc., Chicago, IL). Mann–Whitney U and Kruskal–Wallis nonparametric data analyses were used for analysis of variables accordingly in addition to the chi-square test. All data are presented as mean ± SD. Statistical significance was considered at $P < 0.05$.

Results

The two studied groups were similar in age, sex, weight, and height (table 2). Facemask ventilation before the laryngeal mask insertion in all patients was easy, and no patient needed an oral airway to maintain the airway. In two patients (one in each group), a continuous leak of the airway existed because a good seal could not be obtained, and intubation was chosen. Data from these patients have been excluded, and the cases were repeated. In all other patients, adequate insertion of the laryngeal mask was obtained. The overall laryngeal mask insertion time was within 20 s and successful on the first insertion attempt in 97% of the *LMA-Classic™* group and 95% of the Soft Seal LM group (table 2). In 3% of the *LMA-Classic™* group and 5% of the Soft Seal LM group,

Table 2. Demographic and Overall Patient Data

	LMA-Classic™ (n = 100)	Soft Seal LM (n = 100)	*P* Value*
Male:female ratio	29:71	28:72	NS
Age, yr	46.3 ± 16.3	44.4 ± 16.4	NS
Weight, kg	70.8 ± 9.1	68.3 ± 9.5	NS
Height, cm	167.7 ± 8.4	165.3 ± 6.1	NS
Duration of anesthesia, min	59.6 ± 27.9	61.5 ± 32.5	NS
Minimum–maximum, min	20–140	20–140	NS
Ease of insertion			
Very easy at first attempt (no resistance)	70%	67%	NS
Easy at first attempt (little resistance)	27%	28%	NS
Difficult but successful at second attempt	3%	5%	NS
Not successful	—	—	
Insertion time within 20 s	97%	95%	NS
Mean cuff pressure, mmHg			
At start of surgery	45.0	45.0	NS
At end of surgery	100.3 ± 23.6	46.8 ± 3.6	<0.001
Blood on LM at time of removal, No.	4	0	NS

* Mann–Whitney U test.

LM = laryngeal mask; NS = not significant.

laryngeal mask insertion was only successful at the second attempt. The insertion of the Soft Seal LM became easier with time and experience. The laryngeal mask could be passed in the hypopharynx in all patients. In no case in either group did insertion of the laryngeal mask provoke laryngeal spasm or retching. No significant differences were seen in the hemodynamic and respiratory data in patients of both groups, and there were no events of desaturation during the trial. None of the patients needed a muscle relaxant at the time of insertion of the laryngeal mask. However, in 8% of the patients in the *LMA-Classic™* group and 9% of the patients in the Soft Seal LM group, muscle relaxants were used because of surgical indications, but only well after the insertion and the clinical and fiberoptic evaluation of the laryngeal mask. Ventilation was well tolerated, and its use did not show any adverse effect, nor did it affect the results.

The mean laryngeal mask cuff pressure increased from 45 mmHg to 100.3 ± 23.6 mmHg in the *LMA-Classic™* group and from 45 mmHg to 46.8 ± 3.6 mmHg in the Soft Seal LM group ($P < 0.001$) at the end of surgery (table 2). The presence of macroscopic blood on removal of the mask (4%) was only seen in the *LMA-Classic™* group (table 2).

Sore throat at 2 h in the postoperative period was seen more frequently ($P < 0.05$) in the *LMA-Classic™* group (20.5% *vs.* 10.2%; table 3). Mild sore throat, including dryness of the mouth, not requiring any treatment, was mentioned in 11 patients in the *LMA-Classic™* group *versus* 10 in the Soft Seal group. In the *LMA-Classic™* group, six patients had moderate pain, and three patients had severe pain of the throat. No statistically significant difference between the two groups at 24 h was observed (table 3).

At the time we checked the fiberoptic anatomic position of the laryngeal mask, we did not see any suspected or proved episodes of aspiration, regurgitation, or vomiting, although frequently, material was emerging from the trachea lumen into the hypopharynx, and saliva could be seen collecting in the hypopharynx. Although in 6% of the *LMA-Classic™* and 4% of the Soft Seal LM cases the vocal cords could not be made visible by fiberoptic examination, satisfactory anesthesia was never a problem. The outcome of the fiberoptic examination did not reach statistical difference between the two groups (table 4).

Table 3. Comparison of Postoperative Sore Throat Incidence between Soft Seal LM Group and *LMA-Classic*™ Group at 2 h and at 24 h

	At 2 h	At 24 h
	LMA-Classic™/ Soft Seal LM	*LMA-Classic*™/ Soft Seal LM
Postoperative sore throat incidence		
None	79.5/89.8	80.3/86.3
Mild	11.4/10.2	9.2/14.7
Moderate	5.7/0	6.6/0
Severe	3.4/0	3.9/0
P value (Kruskal-Wallis test)	0.041	0.302 (NS)

LM = laryngeal mask; NS = not significant.

Table 4. Outcome of Fiberoptic Examination of Position of Two Laryngeal Masks

Epiglottis Position*	*LMA-Classic*™, No.	Soft Seal LM, No.
Grade 4	51	43
Grade 3	31	47
Grade 2	12	6
Grade 1	6	4

* Not significant, Mann–Whitney U test ($P = 0.712$).

Discussion

This is the first report on the use of a new disposable laryngeal mask, the Soft Seal LM, in which we conducted a clinical comparison of the reusable *LMA-Classic™* and the new disposable Soft Seal LM size 4 and found that both laryngeal masks provided an adequate airway and similar clinical performance in spontaneously breathing patients. The Soft Seal LM was less traumatic, causing less sore throat in the early postoperative period.

Insertion Technique

It is a common practice to inflate the laryngeal mask cuff to the maximal recommended volume,[3] while intracuff pressures are rarely measured and maintained in clinical practice. This often results in high intracuff pressures, up to 250 mmHg,[17] possibly leading to increased mucosal pressure,[2,27] pharyngolaryngeal trauma,[13-14,27] and a suboptimal seal.[3] In the past, we used this high recommended cuff volume practice until we found out that the majority of our patients had cuff pressures greater than 120 cm H_2O (90 mmHg) immediately after insertion of the laryngeal mask. Many authors now recommend inserting the laryngeal mask with the cuff partially inflated.[3,11-18]

During anesthesia, a significant increase in cuff pressure is seen because of the presence of nitrous oxide, carbon dioxide, or other gases and because of the warming up of these gases. Avoiding high intracuff pressures and volumes during nitrous oxide anesthesia results in a better outcome for the patient (more optimal seal and less pharyngolaryngeal trauma).[3,14-17] Some investigators show that high laryngeal mask pressures do not increase pharyngeal mucosal injury in dogs,[28] while others suggest reducing the cuff volume to a "just seal" situation.[29]

We, too, believe that insertion of the laryngeal mask airway with the cuff partially inflated is equally successful to insert the laryngeal mask and results in a lower incidence of sore throat and pharyngeal mucosal bleeding. This might be the result of the presentation of a softer leading edge to the posterior pharyngeal wall.

Sore Throat

The incidence of sore throat using the *LMA-Classic™* in our study was 20%, which is identical to the findings of Brimacombe *et al.*[15] when the cuff is partially inflated, compared to 42% if the cuff was fully inflated after insertion. Our incidence of sore throat with the Soft Seal LM is even lower (*i.e.*, 10%), which is similar to the incidence of sore throat after the use of a facemask (*i.e.*, 8%) in the studies of Brimacombe *et al.*[15] and Dingley *et al.*[30]

Using the standard approach technique, with the insertion of a noninflated *LMA-Classic™*, the reported incidence of sore throats ranges between 21.4% and 30% according to Wakeling *et al.*,[13] 28.5% in the study of Dingley *et al.*,[30] and up to 42% as measured by Brimacombe *et al.*[15] The sore throat incidence is less when the cuff is partially inflated compared to noninflated cuffs, *i.e.*, 4.1% *versus* 21.4% as demonstrated by Wakeling *et al.*[13]

Materials

The Soft Seal LM is translucent, allowing easier visualization of any secretions inside it. On the disposable laryngeal mask, the size of the product and maximum cuff inflation volume are printed on the pilot balloon, allowing the clinician to recognize its size once *in situ* (fig. 1). Although the IDs of the *LMA-Classic™* and the Soft Seal LM are identical (11.0 mm), *in vitro* a 7.0-mm cuffed endotracheal tube can be inserted into the disposable laryngeal mask, while only a 6.0-mm endotracheal tube can be inserted into the shaft of the *LMA-Classic™*.

Fiberoptic Examination of the Position of the Laryngeal Mask

Patients with a "high" or "anterior" larynx did not always show a complete view of the larynx inlet by fiberoptic examination through the laryngeal mask in our study. However, the number of patients whose vocal cords were not visible was not significantly different between the two groups, confirming that insertion of both laryngeal masks results at least in the same position. All laryngeal masks used in this study resulted in adequate ventilation. This confirms that the absence of epiglottic bars have no deleterious effects on the performance of the laryngeal mask.[31] Blockage of the airway tube by the epiglottis may be avoided by the deeper bowl, as is the case with the disposable laryngeal mask.

Limitations of the Study

We only compared size 4 laryngeal masks because this was the only size of disposable laryngeal mask available at the time of our study. For obvious financial reasons, we compared new disposable laryngeal masks with reusable *LMA-Classic™*. The *LMA-Classic™* may become more permeable to nitrous oxide the more it is used. The anatomic position of the LMA by fiberoptic evaluation was restricted to the view obtained from the tube of the laryngeal mask, limiting the results. We did not evaluate whether the use of a different lubricant on the LMA before insertion resulted in more or less pharyngolaryngeal trauma.

In conclusion, disposable laryngeal masks are an acceptable device to replace the reusable *LMA-Classic™*, resulting in a good laryngeal seal and similar clinical performance. The absence of epiglottic bars seems not to have deleterious effects on the performance of the laryngeal mask. Our study also shows that measuring cuff pressures of laryngeal masks may be advisable when

reusable *LMA-Classic™* masks are used, but this is unnecessary with the disposable Soft Seal LM.

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